

REMARKS

In the Office Action issued on September 30, 2009, the Examiner:
rejected Claim 37 under 35 U.S.C. §102(e) as being anticipated by United States Patent Application Publication No. 2003/0040792 ("Gabbay").

Applicants have fully considered the Office Action and cited reference and submit this Reply and Amendment in response to the Examiner's action. Reconsideration of the application for patent is requested.

Amendments to the claims

The Applicants have herein amended independent claim 37 to more particularly point out and distinctly claim that which the Applicants regard as their invention for this particular claim. Specifically, claim 37 has been amended to clarify that the orientation of the valve prosthesis within the delivery apparatus is determined relative to the distal end of the delivery apparatus.

All of the amendments to claim 37 are fully supported by the application as originally filed; no new matter has been introduced. Exemplary support is found in paragraphs [0056], [0057], and [0058], and in Figures 20, 21, and 23.

Status of Gabbay as prior art

Applicants address Gabbay herein solely to establish that it fails as an anticipatory reference because it fails to disclose each and every limitation of the rejected claim. Applicants make no admission that Gabbay qualifies as prior art and reserve the right to swear behind the reference as permitted by law.

Rejections of the claims under §102

The Examiner rejected independent claim 37, the sole remaining claim, under 35 U.S.C. §102(e) as being anticipated by Gabbay.

To properly anticipate a claim under §102, a prior art reference must disclose, either expressly or inherently, each and every element and limitation of a claim. (MPEP, §2131; *see Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). While identity of terminology between the claim and the reference is not required, the reference must have the elements arranged as required by the claim. (MPEP §2131; *see In re Band*, 910 F.2d 831 (Fed. Cir. 1990)).

Claim 37 explicitly requires:

"determining the orientation of the valve prosthesis within the delivery apparatus relative to the distal end of the delivery apparatus;" and

"verifying that the determined orientation of the valve prosthesis is indicative of a delivery approach specified by indicia located on at least one of the delivery apparatus, the valve prosthesis, and the packaging material thereof."

Gabbay does not disclose, either explicitly or inherently, either of these steps. The reference does not describe any step relating to the determination of an orientation of the prosthesis *relative to the distal end of the delivery apparatus*. It also fails to describe any step relating to a verification that a determined *orientation of the prosthesis is indicative of a delivery approach specified by relevant indicia*.

Indeed, the description pointed to by the Examiner refers only to the use of "imaging technology" to *position the valve at a desired position within a body vessel*. As described by Gabbay:

The catheter may then be used to position the valve at a desired position, such as by utilizing a suitable imaging technology (e.g., x-ray, ultrasound, or other tomography device) or a direct line of sight. Once at the desired

position, the prosthesis 300 may be discharged from its retaining mechanism (e.g., an enclosure) so that it expands toward its original expanded configuration at the desired position within the aorta 306.

(Gabbay, paragraph 0073)

This “positioning” bears no relation to a determination of prosthesis orientation relative to the delivery apparatus or to a verification of a delivery approach specified by relevant indicia. Applicants respectfully assert that this mentioning of “imaging technology” is not an explicit or inherent disclosure of the orientation determination and verification steps that are required by claim 37. For at least this reason, Gabbay fails to anticipate claim 37.

Applicants also note that the “imaging technology” described by Gabbay is used *after* the delivery apparatus has been introduced into a body vessel of the patient. Claim 37 is explicitly directed to “verifying the orientation of a valve prosthesis within a delivery apparatus *prior to introduction into a patient.*”

Consequently, Gabbay does not disclose each and every element of independent claim 37, the sole remaining claim. For at least the reasons stated above, the reference cannot properly serve as a basis for rejection under §102. Applicant respectfully requests withdrawal of this rejection and reconsideration of the application for patent.

CONCLUSION

The Applicants have fully responded to the rejections listed by the Examiner in the September 30, 2009 Office Action. A Notice of Allowability is appropriate and is respectfully requested by the Applicants.

Should the Examiner have any questions regarding this Reply and Amendment, or the remarks contained herein, the undersigned attorney would welcome the opportunity to discuss such matters with the Examiner.

Respectfully submitted,

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